

INTERVIEW SUMMARY

Applicant thanks Examiner Q. Janice Li for the courtesy of the telephonic interview, held November 14, 2006 between the Examiner and Applicant's representatives, Lawrence S. Graham and Nikolaos C. George (collectively, "Applicant's representatives"). Applicant's representatives discussed the pending non-final Office Action with the Examiner. The Examiner indicated that amending claim 24 to recite the limitations of claim 29 would obviate all of the pending rejections, including the rejections under 35 U.S.C. § 112, first paragraph. Applicant's representatives agreed to so amend the claims, and to amend the claims to specify that the recited placental stem cells comprise CD34⁺ stem cells. With respect to the composition claims, the Examiner indicated that an additional search of the art would be performed, though Applicant's representatives pointed out that prior searches would have revealed any art identifiable in a new search. Applicant's representatives agreed to file a formal response to the pending Office Action.

REMARKS

Claims 24-50 are currently pending in the application. Claims 29 and 46-50 are canceled herein without prejudice. Claim 24 is amended to specify that the placental stem cells recited therein comprise CD34⁺ stem cells that are OCT-4⁺, SSEA3⁺ or SSEA4⁺. Support for the amendment to claim 24 is found in claim 29, and in the specification at least at pages 4 and 28. Claim 30 is amended to depend from claim 24, and to conform dependency to claim 24. Claim 31 is amended to specify that the method comprises seeding CD34⁺ stem cells onto the recited tissue matrix. Support for the amendment to claim 31 is found in the specification at least at page 3, lines 21 to page 4, line 11, and page 28. Claims 41-45 are amended to correctly depend from claims 25, 27, 28, 24 and 26, respectively. New claims 51-57 are added. Support for new claims 51-57 is found in the specification at least at page 3, lines 21 to page 4, line 11, and page 28. No new matter is thus introduced by these amendments.

Attorney Docket Number

The Office Action cover sheet indicates that the Attorney Docket Number is 011307. Please amend the Attorney Docket Number for this application to **9516-101-999**.

totipotent stem cell should be able to generate embryoid or embryoid-like bodies.” Office Action at page 3. Applicant notes that Huss never states or suggests that the stem cells discussed therein produce embryoid bodies or embryoid-like bodies. Thus, there is no evidence on record that the stem cells discussed in Huss actually do or can form embryoid or embryoid-like bodies. Moreover, Huss itself only speculates as to the CD34⁻ mesenchymal stem cells’ potency; the reference fails to disclose any *proof* that such stem cells have the capacity to “generate whole organ systems”. Thus, Huss is not evidence that one of skill in the art would not recognize that Applicant has adequately described the recited placental stem cells. As such, Huss does not evidence any lack of written description of the claims as amended.

For the above reasons, Applicant respectfully requests that the Examiner withdraw this rejection of the claims.

The Rejections Under 35 U.S.C. § 112, Second Paragraph Should Be Withdrawn

Claims 24-31 and 35-50 are rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite. Office Action at page 3. At the outset, Applicant notes that claims 29 and 46-50 have been canceled without prejudice.

Specifically, the Examiner contends that the term “flush” in claim 24 is indefinite in that “[t]he specification fails to define the condition for ‘flush’, it is unclear what step(s) are encompassed by ‘flush’, and thus the metes and bounds of the claims are uncertain.” *Id.* Without conceding the propriety of

1304 (Fed. Cir. 2002); *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292 (Fed. Cir. 2002).

Without conceding the propriety of the Examiner's rejection, and solely to facilitate prosecution of the claims, Applicant has amended claim 24 to specify that the method comprises seeding a tissue matrix with placental stem cells that comprise CD34⁻ stem cells that are SSEA3⁻, SSEA4⁻, or OCT4⁺. Pykett does not disclose cells that are CD34⁻ that are CD34⁻ and either SSEA3⁻, SSEA4⁻, and/or OCT4⁺, or matrices comprising such cells. Indeed, Pykett only discloses the use of hematopoietic stem cells. As such, Pykett only discloses the use of stem cells that are CD34⁺. Thus, Pykett does not anticipate claim 24 as amended. Because Pykett does not anticipate claim 24, the reference does not anticipate any of claims 25-27 and 31-36, each of which ultimately depends from claim 24. Applicant therefore respectfully requests that the Examiner withdraw the rejection of the claims on this basis.

The Rejection Under 35 U.S.C. § 103 Should Be Withdrawn

The Examiner has rejected claims 24, 26-28, and 35-40 as obvious over Pykett in view of Goldstein *et al.* (U.S. Patent No. 5,899,9

obvious. Because claim 24 is not obvious over the cited references, claims depending from claim 24 are nonobvious, as well. *In re Fine*, 837 F.2d at 1071.

Applicant therefore respectfully requests that the Examiner withdraw this rejection of the claims.

The Rejection Under 35 U.S.C. 102/103 Should Be Withdrawn

The Examiner has rejected claims 41-50 under 35 U.S.C. 102(e) as anticipated by, or under 35 U.S.C. 103 as obvious over, Anderson *et al.* (U.S. Patent No. 6,328,762; “Anderson”) as evidenced by Huss. Office Action at pages 6-8. At the outset, Applicant notes that claims 46-50 have been canceled without prejudice.

The Examiner contends that Anderson teaches a tissue matrix (that is, a porous prosthetic implant) seeded with, *e.g.*, stem cells from bone marrow or mesenchymal stem cells. Office Action at page 6. The Examiner further contends that Huss teaches that “CD34⁻ bone marrow cells contains [*sic*] a population of stem cells that are totipotent.” Office Action at page 6.

As noted above, Applicant has amended claim 24 to specify that the recited placental stem cells comprise CD34⁻ stem cells that are SSEA3⁻, SSEA4⁻

The Objections to the Claims Should Be Removed

The Examiner states that “[c]laims 29 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form . . .”. Office Action at page 9. Claim 30 depends from claim 29. Applicant has amended claim 24 to include the limitations of claim 29. Thus, claim 24, as amended, should be allowable. As the rejections of the remaining claims, which ultimately depend from claim 24, do not rest on the specific limitations of those claims, claims depending from claim 24 are also allowable. Applicant therefore respectfully requests that the Examiner withdraw this objection to the claims.

CONCLUSION

Applicant respectfully requests that the above remarks and accompanying documents be entered in the present application file. An early allowance of the present application is respectfully requested. No fee is believed due in connection with this Amendment. However, if any fee is deemed to be due, please charge such fee to Jones Day Deposit Account No. 503013.

Respectfully submitted,

Date: December 14, 2006